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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,561	01/15/2004	David M. Weiner	ACADIA.030A	8108

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
07/11/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary	Application No.	Applicant(s)	
	10/759,561	WEINER ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 48-89* is/are pending in the application.

4a) Of the above claim(s) *49-89* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed January 10, 2008 have been received and entered into the application. Newly added claims 87-89 are withdrawn from consideration since they read on the non-elected invention.

Applicant's arguments with respect to claims 1-8 and 48 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 48 is rejected under 35 U.S.C. 102(b) as being anticipated by R&D Focus Drug News (12 Nov. 2001).

R&D Focus Drug News teaches the compound set forth in claim 48, ACP 103, is a selective 5HT2A inverse agonist and has a potential antipsychotic agent with an improved side-effect profile. R&D Focus Drug News teaches that ACP 103 was found to be orally bioavailable with a high efficacy, in animal models of psychosis.

Claim 48 is rejected under 35 U.S.C. 102(b) as being anticipated by R&D Focus Drug News (24 Jan 2000).

R&D Focus Drug News teaches pimavanserin tartrate (ACP 103) has been identified as a lead compound within its program to develop as an antipsychotic drug.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over R&D Focus Drug News (12 Nov. 2001) in view of Anderson et al. (WO0166521-IDS 01/18/2005) of record and further in view of and further in view of Goodman and Gilman's The Pharmacological Basis of Therapeutics, 7th edition, pages 340-343 and 403-404 of record.

R&D Focus Drug News teaches the compound set forth in claim 1, ACP 103, is a selective 5HT2A inverse agonist and has a potential antipsychotic agent with an improved side-effect profile. R&D Focus Drug News teaches that ACP 103 was found to be orally bioavailable with a high efficacy, in animal models of psychosis.

R&D Focus Drug News does not expressly teach a pharmaceutically acceptable carrier and an additional therapeutic agent and the additional agents set forth in claims 3-8.

Anderson et al. teach that the compounds broadly including, ACP 103 can be formulated with pharmaceutically acceptable insert carrier such as ethanol, glycerol, water and the like. Anderson et al. teach that when desired or necessary, suitable binders, lubricants, disintegrating agents, flavoring agents and disintegrating agents can be also incorporated into the mixture comprising the compound. (page 29, lines 27-30). Anderson et al. teach on pages 9-12, compounds of formula I that broadly encompasses the currently disclosed formula I and suitable pharmaceutically acceptable salts such including hydrochloride and tartrate. (Page 27, line30-page 28 line 14). On page 32 lines 12-25, Anderson et al. disclose the co-administration of the compounds of formula I with either another compound of formula I or another active agent. One page 6, Anderson et al. disclose that the compounds of formula I are useful for treating variety of diseases and disorders including schizophrenia, depression, anxiety, sleep disorder, etc. Anderson et al. disclose that the formula I, avoid the adverse side effects such as dyskinesia, tremor and dystonic reactions. (page 4, lines 28-33, page 3, lines 9-10). The therapeutic applications: neurodegenerative disease, psychosis, schizophrenia, depression and affective disorders are explicitly mentioned to be treatable with compounds of Anderson et al.

Goodman and Gilman's teaches, on page 340-343 teach, benzodiazepines useful in the treatment of anxiety, muscle relaxation and anticonvulsive therapy. On page 342, clonazepam is taught as a particularly good muscle relaxant. On page 343, it is disclosed that benzodiazepines increase the net total sleep time, making them

unsuitable as agents for sleep disorders. Goodman and Gilman's teaches, on page 403-404, several anti-psychotic agents including Thorazine, Mellaril, Haldol, etc.

It would have been obvious to one of ordinary skill in the art to modify the teaching of R&D Focus Drug News and formulate a pharmaceutical composition comprising ACP 103 by combining a pharmaceutically acceptable insert carriers for treatment of psychosis because R&D Focus Drug News teaches the compound, ACP 103, was found to be orally bioavailable with a high efficacy, in animal models of psychosis and because Anderson teaches that the general compounds including ACP 103 can be combined with a pharmaceutically acceptable carrier for oral administration. One would have been motivated to make such a modification in order to achieve an expected antipsychotic benefit of the ACP 103 in oral formulation with a benefit of having an improved side-effect profile. There is a reasonable expectation of successfully formulating ACP103 with a pharmaceutically acceptable carrier as an antipsychotic agent because there is a clear teaching from R&D Focus Drug News that ACP 103 was found to be orally bioavailable with a high efficacy, in animal models of psychosis. With respect to incorporation of additional agents set forth in claim 3-8 are obvious because Anderson et al. disclose that coadministration of the compounds of formula I with other active agents and that the compound formula I is useful for the treatment of psychosis and related disorders such as neurodegenerative disease, psychosis, schizophrenia, depression and affective disorders and dyskinesia, tremor and dystonic reactions as taught by Anderson et al. It is noted that Goodman and Gilman teaches the additional agents are also useful for the treatment of various

conditions including psychosis, anxiety, sleep disorder and conditions related to psychosis. The motivation for combining the components flows from their individually known common utility (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Inventorship

In view of the papers filed June 20, 2008, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a).

The inventorship of this application has been changed by addition of:

Carl-Magnus A. Andersson
Ferievagen 3
SE-245 64 Hjarup, Sweden

and

Allan K. Uldam
Skotteparken 172
2750 Ballerup, Denmark.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Communication

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Kim/
Primary Examiner, Art Unit 1617

Jmk
July 7, 2008